REMARKS

In the Final Office Action, the Examiner rejected claims 6, and 9-13 under 35 U.S.C. §102(e) as being anticipated by Norris (WO 01/65441). Applicants respectfully traverse each and every rejection included in the Final Office Action. By this amendment, Applicants have amended the specification and amended claims 6, 9, 10, and 13. Claims 6 and 9-13 remain pending. Applicants respectfully submit that, as amended, the pending claims are in condition for allowance and request reconsideration and allowance of this application.

A. Norris Does not Select a Second Main Ingredient For Use in Prototyping a Product that Includes a First Main Ingredient

There is a fundamental distinction between Norris and the invention recited in the amended claims. Norris has no concern for confidentiality of the performance characteristics of the main ingredient—to the contrary, Norris discloses a system with the objective of broadcasting those characteristics to as wide a market as possible to increase sales of the main ingredient. A primary objective of the present invention, on the other hand, is to maintain the security of the main ingredient (and the pharmacological effect) so as to permit access to secondary ingredients during the process of prototyping the ultimate product without revealing confidential information regarding the main ingredient. These two objectives are diametrically opposed to one another.[1]

[1] While the Applicants do not necessarily agree with the Examiner's conclusions in paragraph 8 of the final Office Action, they have focused these remarks on this fundamental failing of the Norris reference. Applicants reserve their right to further address the positions of the Final Office Action.

The Examiner relies on Norris page 5, lines 1-5 and page 7, line 23-26 to anticipate all pending claims 6 and 9-13. Applicants respectively disagree.

Norris at page 5, line 1-5 merely is introducing the idea that formulations or formulation components may be selected and that this selection process requires "an understanding of how the selected components effect performance." Applications do not dispute that this concept was known.

Norris at page 7, lines 23-26 merely is introducing the idea that components of a formulation are purchased "in the context of the utility derived from its interaction with other components of a given formula." Again Applicants do not dispute that this concept was known.

But the conclusion of the Examiner, that "[u]nder such conditions the prior art teaches selecting a second main ingredient having a different pharmacological effect than the first main ingredient," is both illogical and irrelevant to the patentability of the present invention as claimed. It is illogical because a customer using Norris' system to develop a medicine having a particular pharmacological effect would select components directed toward having that desired effect. Indeed, Norris teaches the selection of formulations based on their intended use. (*See, e.g.,* Norris at page 16, lines 4-6.)

But more importantly, the Examiner's conclusion is irrelevant. Nothing in Norris suggests a system that receives a request for a prototype manufacture of a product including the first main ingredient "from the product manufacturer" and then—after selecting a second main ingredient that has a different pharmacological effect—transmitting that second main ingredient "to a composition manufacturer," as the claims of the present application require. Why would the Norris system, in the process of

developing a prototype **using the first main ingredient**, send **the second main ingredient** to anyone, much less to a "composition manufacturer"?

Apparently, the Examiner is reading the claims as just replacing the "first main ingredient" with a "second main ingredient" in the process of developing medical product. If this were correct, the "first main ingredient" would have no role in the development and the "second main ingredient" would be in the final product. But this is not the case. Indeed, as amended, the claims recite "a medical product including a confidential first ingredient." The whole point of the present invention is for prototype development of a product including the "first main ingredient" and the pharmacological effects of that ingredient. This is done while maintaining securing of those pharmacological effects by using a bogus, pharmacologically different "second main ingredient" during prototyping, as claimed.

As amended, Claims 6 and 9 recite a "medicine prototype support system for an ingredient manufacturer developing a medical product including a confidential first main ingredient at a request of a product manufacturer" that does not reveal the identity of the main ingredient to be included in the final product. The systems recited in claims 6 and 9 are configured to receive a first request for prototype manufacture including information regarding the confidential first main ingredient from the product manufacturer, but to transmit a second request for prototype manufacture including the information regarding the second main ingredient to a composition manufacturer. Thus, in developing a prototype for the manufacture of a medical product including the first main ingredient, the claimed systems substitute a second main ingredient—having a

"different pharmacological effect than the confidential first main ingredient"—in its place. This is not taught by Norris.

The method of claim 10 requires the steps of "receiving a first request for prototype manufacture from a computer system of a product manufacturer ... including medical product information regarding the first main ingredient," but "transmitting a second request for prototype manufacture to a computer system of a composition manufacturer ... including the identities of the selected second main ingredient and the selected composition ingredient." Thus, unlike Norris, the method of claim 10 requires that information regarding the second main ingredient be included in a request for manufacture of a prototype for a product that will ultimately include the first main ingredient. Claims 11-12 are allowable at least due to their dependence from claim 10.

Finally, the system of claim 13 requires "information conversion means ... for converting main ingredient information to be transmitted to a computer system of a composition manufacturer from information regarding the confidential first main ingredient included in a request from the product manufacturer to information regarding the second main ingredient stored in the database." Thus, like the other claims discussed above, claim 13 requires the use of a second main ingredient while developing a prototype for "a medical product including a confidential first main ingredient." Accordingly, claim 13 is distinguishable from Norris.

B. Norris does not Teach the Two-Step Conversion of Amended Claim 6

As amended, claim 6 requires that the information conversion means select a second main ingredient "by selecting an intermediate main ingredient having one or more material properties similar to the confidential first main ingredient and then

selecting a second main ingredient having one or more material properties similar to the intermediate main ingredient, but having a different pharmacological effect than the confidential first main ingredient." This amendment finds support, for example, at page 29, lines 11-22 of the application, which describes converting the main ingredient X1 (verapamil hydrochloride) of a medical product into an intermediate main ingredient X'1 (dilazeph hydrochloride) and then converting the intermediate main ingredient X'1 into a second main ingredient X"1 (acetaminophen) having a different pharmalogical effect than the first main ingredient X1.

Norris, in contrast, teaches selecting multiple products having similar intended uses and presenting all of the selected products to a potential customer. (*See, e.g.,* Norris at page 16, lines 4-6.) It does not disclose or suggest the two-step conversion recited in amended claim 6, wherein the information conversion means first selects "an intermediate main ingredient having one or more material properties similar to the confidential first main ingredient" and then selects "a second main ingredient having one or more material properties similar to the intermediate main ingredient, but having a different pharmacological effect than the confidential first main ingredient." Instead, Norris compares each formulation with the intended use suggested by the customer, without regard to obscuring the identity of a confidential first main ingredient from a component manufacturer. Claim 6 is allowable over Norris for at least this additional reason.

C. Conclusion

For at least these reasons, the pending claims are allowable over Norris. In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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